

Docket No.: 03235/100M087-US2

(PATENT)

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:

Charles A. Altar et al.

Application No.: 10/664,705

Filed: September 18, 2003 Art Unit: 1649

For: GENE SIGNATURE OF ELECTROSHOCK

THERAPY AND METHOD OF USE

Examiner: S. H. Standley

Confirmation No.: 5502

## TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

In order to comply with the duty to disclose information under 37 C.F.R. § 1.56, Applicants submit herewith an Information Disclosure Statement pursuant to the requirements of 37 C.F.R. §§ 1.97 and 1.98. In particular, Applicants submit herewith Form PTO/SB/08a/b (Substitute for Form 1449A/B/PTO) listing documents AA-CR for consideration by the Examiner. Copies of cited documents AC-CR are also submitted herewith. In order to avoid overburdening the Examiner, copies of documents AA and AB are not submitted herewith since these documents are U.S. patents. See 37 C.F.R. § 1.98(a)(2)(ii). However, Applicants will gladly provide copies of these references at the Examiner's request.

It is believed that this Information Disclosure Statement is being submitted before the mailing date of a first Office Action on the merits and in accordance with the provisions of 37 C.F.R. § 1.97(b)(3). It is therefore believed that no fee is required for this submission. However, should it be determined that any fee is required for this application or that any refund is owed, then

Application No. 10/664,705 Transmittal of Information Disclosure Statement

the Commissioner is hereby requested and authorized to charge the required fee(s) and/or credit the refund(s) due to Deposit Account No. 04-0100 of Applicants' undersigned attorneys/agents.

It is respectfully requested that each document cited in this Information Disclosure Statement be given thorough consideration by the Examiner, and that each document be cited of record in the prosecution history. Although this Information Disclosure Statement is being submitted in compliance with 37 C.F.R. § 1.56, the citation of a document is not to be construed as an admission that such document is necessarily relevant or that the document is "prior art" to the present application. No representation is intended that the documents cited in the Information Disclosure Statement represent the results of a complete search, or that any search has been made.

Dated: October 26, 2005

Respectfully submitted,

Samuel S. Woodley, Ph.D. Registration No.: 43,287

DARBY & DARBY P.C.

P.O. Box 5257

New York, New York 10150-5257

(212) 527-7700

(212) 527-7701 (Fax)

Attorneys/Agents For Applicant

OCT 2 6 7005 W

PTO/SB/08a/b (07-05) Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Su	bstitute for form 1449A/B/P	то		Complete if Known		
"				Application Number	10/664,705	
l II	NFORMATIO	N DI	SCLOSURE	Filing Date '	September 18, 2003	
l s	STATEMENT	BY /	APPLICANT	First Named Inventor	Charles A. Altar	
				Art Unit	1649	
	(Use as many si	heets as	s necessary)	Examiner Name	S. H. Standley	
Sheet	1	of	5	Attorney Docket Number	03235/100M087-US2	

	U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No.1	Document Number  Number-Kind Code <sup>2</sup> ( if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear		
	AA*	US-5,859,197	01-12-1999	Theill et al.			
	AB*	US-5,817,784	10-06-1998	Theill et al.			

	FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No.1	Foreign Patent Document  Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T⁵			

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at <a href="https://www.uspto.gov">www.uspto.gov</a> or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

		NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>		
	AC	FOCHTMANN, "Animal Studies Electroconvulsive Therapy: Foundations for Future Research," Psychopharmacology Bulletin, Vol. 30 No. 3, 321-381 (1994)			
	AD	BIEGON et al., "Localization of the Effects of Electroconvulsive Shock on ß-Adrenoceptors in the Rat Brain," European Journal of Pharmacology, 123:329-334 (1986)			
	AE	ALTAR et al., "Efficacy of Brain-Derived Neurotrophic Factor and Neurotrophin-3 on Neurochemical and Behavioral Deficits Associated with Partial Nigrostriatal Dopamine Lesions," Journal of Neurochemistry, 63:1021-1032 (1994)			
AF MAMOUNAS et al., "Brain-Derived Neurotrophic Factor Promotes the Survival and Sprou of Serotonergic Axons in Rat Brain," The Journal of Neuroscience, 15 (12):7929-7939 (19)					
AG MARTIN-IVERSON et al., "Brain-derived Neurophic Factor and Neurotrophin-3 Activate Striatal Dopamine and Serotonin Metabolism and Related Behaviors: Interactions with Amphetamine," The Journal of Neuroscience, 14 (3):1262-1270 (1994)					
	АН	SIUCIAK et al., "Antidepressant-Like Effect of Brain-derived Neurotrophic Factor (BDNF)," Pharmacology Biochemistry and Behavior, Vol. 56, No. 1, 131-137 (1997)			
	Al	ROCAMORA et al., "Limbic seizures induce a differential regulation of the expression of nerve growth factor, brain-dervied neurotrophic factor and neurotrophin-3, in the rat hippocampus," Molecular Brain Research, 13:27-33 (1992)			
	AJ HENDRIKSEN et al., "Altered hippocampal gene expression prior to the onset of spontaneous seizures in the rat post-status epilepticus model," European Journal of Neuroscience, Vol. 14, 1475-1484 (2001)				
	AK LUKASIUK et al., "cDNA profiling of epileptogenesis in the rat brain," European Journal of Neuroscience, Vol. 17, 271-279 (2003)				
	AL	KIM et al., "Electroconvulsive Shock Reduces Inositol Trisphosphate Receptor1 mRNA in Rat			
Examiner Signature		Date Considered			

PTO/SB/08a/b (07-05)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number. Complete if Known Substitute for form 1449A/B/PTO 10/664,705 Application Number **INFORMATION DISCLOSURE** Filing Date September 18, 2003 STATEMENT BY APPLICANT Charles A. Altar First Named Inventor 1649 Art Unit (Use as many sheets as necessary) S. H. Standley Examiner Name Sheet 2 5 Attorney Docket Number 03235/100M087-US2

	Brain," Mol. Cells, Vol. 12, No. 2, 173-177 (2001)	
AM	JENSEN et al., "Chronic Antidepressant Treatments Decrease Pro-Opiomelanocortin mRNA Expression in the Pituitary Gland: Effects of Acute Stress and 5-HT <sub>1</sub> A Receptor Activation," Journal of Neuroendocrinology, Vol. 13, 887-893 (2001)	
AN	JANG et al., "Isoform Specific Changes of Adenylate Cyclase mRNA Expression in rat Brain Following Chronic Electroconvulsive Shock," Prog. Neuro-Psychopharmacol. & Biol. Psychiat., Vol. 25, 1571-1581 (2001)	
AO	KONDRATYEV et al., "Electroconvulsive shock exposure prevents neuronal apoptosis after kainic acid-evoked status epilepticus," Molecular Brain Research, 91:1-13 (2001)	
AP	KOUBI et al., "Regulation of expression and enzymatic activities of tyrosine and tryptophan hydroxylases in rat brain after acute electroconvulsive shock," Brain Research, 905, 161-170 (2001)	
AQ	SHEN et al., "Electroconvulsive shock regulates serotonin transporter mRNA expression in rat raphe nucleus," Psychiatry and Clinical Neurosciences, 55:75-77 (2001)	
AR	BURNET et al., "Electroconvulsive shock increase tachykinin NK <sub>1</sub> receptors, but not the encoding mRNA, in rat cortex," European Journal of Pharmacology, 413:213-219 (2001)	
AS	Chen et al, "Regulation of GFR $\alpha$ -1 and GFR $\alpha$ -2 mRNAs in Rat Brain by Electroconvulsive Seizure," Synapse, 39:42-50 (2001)	
AT	CHO et al, "Differential changes in the expression of cyclic nucletide phosphodiesterase isoforms in rat brains by chronic treatment with electroconvulsive shock," Experimental and Molecular Medicine, Vol. 32, No. 3, 110-114 (2000)	
AU	LAMMERA et al, "Selective increase of dopamine D3 receptor gene expression as a common effect of chronic antidepressant treatments," Molecular Psychiatry, 5:378-388 (2000)	
AV	MADSEN et al., "Electroconculsive Stimuli Enhance Both Neuropeptide Y Receptor Y1 and Y2 Messenger RNA Expression and Levels of Binding in the Rat Hippocampus," Neuroscience, Vol. 98, No. 1, 33-39 (2000)	
AW	HUSUM et al., "Involvement of hippocampal neuropeptide Y in mediating the chronic actions of lithium, electroconvulsive stimulation and citalopram," Neuropharmacology, 39:1463-1473 (2000)	
AX	VALENTINE et al., "Fragile X (fmr 1) mRNA expression is differentially regulated in two adult models of activity-dependent gene expression," Molecular Brain Research, 75:337-341 (2000)	
AY	BURNET et al., "Expression of 5-HT receptors and the 5-HT transporter in rat brain after electroconvulsive shock," Neuroscience Letters, 277:79-82 (1999)	
AZ	PEI et al., "Alteration in Expression of G-Protein-Activated Inward Rectifier K+-Channel Subunits GIRK1 and GIRK2 in the Rat Brain Following Electroconvulsive Shock," Neuroscience, Vol. 90, No. 2, 621-627 (1999)	
ВА	TAKAHASHI et al., "Chronic Antidepressant Administration Increases the Expression of cAMP-Specific Phosphodiesterase 4A and 4B Isofroms," The Journal of Neuroscience, 19(2):610-618 (1999)	
ВВ	WATKINS et al., "Differential effects of electroconvulsive shock on the glutamate receptor mRNAs for NR2A, NR2B and mGluR5b," Molecular Brain Research, 61:108-113 (1998)	
BC	SUDA et al., "Transcriptional and Translational Regulation of Phosphodiesterase Type IV Isozymes in Rat Brain by Electroconvulsive Seizure and Antidepressant Drug Treatment," Journal of Neurochemistry, Vol. 71, No. 4, 1554-1563 (1998)	
BD	ZETTERSTROM et al., "Repeated electroconvulsive shock extends the duration of enhanced	

Examiner	Date	
Signature	Considered	
Ognature	Considered	

PTO/SB/08a/b (07-05)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Sub	ostitute for form 1449A/B/PT	0		Complete if Known		
				Application Number	10/664,705	
II	NFORMATION	I DI	SCLOSURE	Filing Date	September 18, 2003	
l s	TATEMENT B	3Y <i>A</i>	APPLICANT	First Named Inventor	Charles A. Altar	
				Art Unit	1649	
	(Use as many sh	eets as	necessary)	Examiner Name	S. H. Standley	
Sheet	3	of	5	Attorney Docket Number	03235/100M087-US2	

		gene expression for BDNF in rat brain compared with a single administration," Molecular Brain Research, 57:106-110 (1998)
	BE	GARCIA et al., "Acute and repeated ECS treatment increases CRF, POMC and PENK gene expression in selected regions of the rat hypothalamus," Molecular Neuroscience, Vol. 9, No. 1, 73-77 (1998)
	BF	PEI et al., "Changes in mRNA abundance of microtubule-associated proteins in the rat brain following electroconvulsive shock," Molecular Neuroscience, Vol. 9, No. 3, 391-394 (1998)
	BG	O'DONOVAN et al., "Sequential Expression of Egr-1 and Egr-3 in Hippocampal Granule Cells Following Electroconvulsive Stimulation," Journal of Neurochemistry, Vol. 70, No. 3, 1241-1248 (1998)
	ВН	XING et al., "Rat nurr1 is prominently expressed in perirhinal cortex, and differentially induced in the hippocampal dentate gyrus by electroconvulsive vs. kindled seizures," Molecular Brain Research, 47:251-261 (1997)
	BI	WANG et al., "Electroconvulsive treatment evokes release of preprotachykinin-A mRNA into the cerebrospinal fluid and ocular aqueous humor of rabbits," Neuroscience Letters, 226:151-154 (1997)
	BJ	PEI et al., "Differential Effects of Acute and Chronic Electroconvulsive Shock on the Abundance of Messenger RNAS for Voltage-Dependent Potassium Channel Subunits in the Rat Brain," Neuroscience, Vol. 78, No. 2, 343-350 (1997)
	BK	ZACHRISSON et al., "Decreased Levels of Preprotachykinin-A and Tachykinin NK <sub>1</sub> Receptor mRNA in Specfic Regions of the Rat Striatum After Electroconvulsive Stimuli," European Journal of Pharmacology, 319:191-195 (1997)
,	BL	ZACHRISSON et al., "Effects of Chronic Lithium and Electroconvulsive Stimuli on Cholecystokinin mRNA Expression in the Rat Brain," Molecular Brain Research, 43:347-350 (1996)
	ВМ	JUNG et al., "Induction of Tetradecanoyl Phorbol Acetate-Inducible Sequence (TIS) Genes by Electroconvulsive Shock in Rat Brain," Society of Biological Psychiatry, 40:503-507 (1996)
	BN	MCGOWAN et al., "Hippocampal and Cortical G Protein (G <sub>S</sub> α; G <sub>O</sub> α and G <sub>i</sub> 2α) mRNA Expression After Elctroconvulsive Shock or Lithium Carbonate Treatment," European Journal of Pharmacology, 306:249-255 (1996)
	ВО	WOLDBYE et al., "Prolonged Induction of c-fos in Neuropeptide Y- and Somatostatin- immunoreactive Neurons of the Rat Dentate Gyrus After Electroconvulsive Stimulation," Brain Research, 720-111-119 (1996)
	BP	PORTER et al., "Contrasting Effects of Electroconvulsive Shock on mRNAs Encoding the High Affinity Kainate Receptor Subunits (KA1 and KA2) and Cyclophilin in the Rat," Brain Research, 710:97-102 (1996)
	BQ	NAYLOR et al., "Repeated ECS Induces GluR1 mRNA But Not NMDAR1A-G mRNA in the Rat Hippocampus," Molecular Brain Research, 35:349-353 (1996)
	BR	FITZGERALD et al., "Electroconvulsive Seizure Increases the Expression of CREM (Cyclic AMP Response Element Modular) and ICER (Inducible Cyclic AMP Early Repressor) in Rat Brain," Journal of Neurochemistry, Vol. 66, No. 1, 429-432 (1996)
	BS	CHEN et al., "Regulation of ΔFosB and FosB-like Proteins by Electroconvulsive Seizure and Cocaine Treatments," Molecular Pharmacology, 48:880-889 (1995)
	вт	NIBUYA et al., "Regulation of BDNF and trkB mRNA in Rat Brain by Chronic Electroconvulsive Seizure and Antidepressant Drug Treatments," The Journal of Neuroscience, 15(11): 7539-7547 (1995)
Examiner		Date Considered

Considered

Signature

PTO/SB/08a/b (07-05)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Sut	ostitute for form 1449A/B/P	то		Complete if Known		
"				Application Number	10/664,705	
11	NFORMATIO	N DIS	SCLOSURE	Filing Date	September 18, 2003	
l s	TATEMENT	BY A	APPLICANT	First Named Inventor	Charles A. Altar	
				Art Unit	1649	
	(Use as many si	heets as	necessary)	Examiner Name	S. H. Standley	
Sheet	4	of	5	Attorney Docket Number	03235/100M087-US2	

	BU	SMITH et al., "Electroconvulsive Shock Increases Dopamine D <sub>1</sub> and D <sub>2</sub> Receptor mRNA in
	İ	the Nucleous of the Rat," Psychopharmacology, 120:333-340 (1995)
	BV	BURNET et al., "Repeated ECS Differentially Affects Rat Brain 5-HT <sub>1A</sub> and 5-HT <sub>2A</sub> Receptor
		Expression," Molecular Neuroscience, 6:901-904 (1995)
	BW	LINDEFORS et al., "Spatiotemporal Selective Effects on Brain-Derived Neuothrophic Factor
		and trkB Messenger RNA in Rat Hippocampus by Electroconvulsive Shock," Neuroscience,
		Vol. 65, No. 3, 661-670 (1995)
	ВХ	DZIEDZICKA-WASYLEWSKA et al., "The Effect of Prolonged Treatment with Imipramine and
		Electroconvulsive Shock on the Levels of Endogenous Enkephalins in the Nucleous
		Accumbens and the Ventral Tegmentum of the Rat," J. Neural Transm [Gen Sect], 102:221-
		228 (1995)
	BY	KIM et al., "Electroconvulsive Shock Reduces Inositol 1,4,5-Triphosphate 3-Kinase mRNA
		Expression in Rat Dentate Gyrus," Journal of Neurochemistry, Vol. 63, No. 5, 1991-1994
		(1994)
-	BZ	BRADY et al., "Repeated Electroconvulsive Shock Produces Long-lasting Increases in
		Messenger RNA Expression of Corticotrophin-releasing Hormone and Trypsine Hydroxylase in
		Rat Brain," The Journal of Clinical Investigation, Inc., Vol. 94, 1263-1268 (1994)
	CA	PASSARELLI et al., "Effects of Electroconvulsive Shock on the Levels of hsp70 and hsc73
		mRNA in the Rat Brain," Neuroscience Letters, 177:147-150 (1994)
	CB	MIKKELSEN et al., "Electroconvulsive Shock Increase the Expression of Neuropeptide Y
		(NPY) mRNA in the Piriform Cortex and the Dentate Gyrus," Molecular Brain Research,
		23:317-322 (1994)
	CC	FOLLESA et al., "Regional and Temporal Pattern of Expression of Nerve Growth Factor and
		Basic Fibroblast Growth Factor mRNA in Rat Brain Following Electroconvulsive Shock,"
		Experimental Neurology, 127:37-44 (1994)
	CD	KRAGH et al., "Repeated Electroconvulsive Shocks Cause Transient Changes in Rat
		Hippocampal Somatostatin and Neuropeptide Y Immunoreactivity and mRNA in Situ
	<u></u>	Hybridization Signals," Exp. Brain Res., 98:305-313 (1994)
	CE	BUTLER et al., "Chronic Electroconvulsive Seizures Increase the Expression of Serotonin2
		Receptor mRNA in Rat Frontal Cortex," Journal of Neurochemistry, Vol. 61, No. 4, 1270-1276
	CF	PASSARELLI et al., "Somatostatin mRNA in the Hippocampal Formation Following
		Electroconvulsive Shock in the Rat," Neuroscience Letters, 153:197-201 (1993)
	CG	HOSODA et al., "Regulation of β1-Adrenergic Receptor mRNA and Ligand Binding by
		Antidepressant Treatments and Norepnephrine Depletion in Rat Frontal Cortex," Journal of
		Neurochemistry, Vol. 60, No. 4, 1335-1343 (1993)
	СН	KAPUR et al., "Electroconvulsive Shock Increase Tyrosine Hydroxylase and Neuropeptide Y
		Gene Expression in the Locus Coeruleus," Molecular Brain Research, 18:121-126 (1993)
	CI	PRATT et al., "Electroconvulsive Shock Aalters GABAA Receptor Subunit mRNAs: Use of
		Quantitative PCR Methodology," Brain Research Bulletin, Vol. 30, 691-693 (1993)
	CJ	WONG et al., "Induction of Constitutive Heat Shock Protein 73 mRNA in the Dentate Gyrus by
		Seizures," Molecular Brain Research, 13:19-25 (1992)
	СК	LINDEFORS et al., "Repeated Electroconvulsive Shock Increases Tachykinin and
		Cholecystokinin mRNA Expression in Ventral Periaqueductal Gray," Neuroscience, Vol. 45,
		No. 1, 73-80 (1991)
	CL	KANG et al., "GABAA Receptor mRNAs are Increased After Electroconvulsive Shock,"

Examiner	Date
Signature	Considered

Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Complete if Known Substitute for form 1449A/B/PTO 10/664,705 Application Number **INFORMATION DISCLOSURE** Filing Date September 18, 2003 STATEMENT BY APPLICANT Charles A. Altar First Named Inventor Art Unit 1649 (Use as many sheets as necessary) S. H. Standley Examiner Name Sheet 5 of 5 Attorney Docket Number 03235/100M087-US2

	Psychopharmacology Bulletin, Vol. 27, No. 3, 359-363 (1991)
СМ	COLE et al., "Rapid Rise in Transcription Factor mRNAs in Rat Brain After Electroshock- Induced Seizures," Journal of Neurochemistry, Vol. 55, No. 6, 1920-1927 (1990)
CN	HERMAN et al., "Chronic Electroconvulsive Shock Treatment Elicits Up-Regulation of CRF and AVP mRNA in Select Populations of Neuroendocrine Neurons," Brain Research, 501:235-246 (1989)
СО	XIE et al., "Single or Repeated Electroconvulsive Shocks After the Levels of Prodynorphin and Proenkephalin mRNAs in Rat Brain," Molecular Brain Research, 6:11-19 (1989)
СР	YOSHIKAWA et al., "Electroconvulsive Shick Increases Preproenkephalin Messenger RNA Abundance in Rat Hypothalamus," Proc. Natl. Acad. Sci. USA, Vol. 82, 589-593 (1985)
CQ	Masserano et al., "Electroconvulsive Shock Increases Tyrosine Hydroxylase Activity in the Brain and Adrenal Gland of the Rat," Science, Vol. 214, 662-665 (1981)
CR	NEWTON, et al., "Gene Profile of Electroconvulsive Seizures: Induction of Neurotrophic and Angiogenic Factors", J. Neurosci. 23(34):10841-51 (2003).

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Examiner	Date
Signature	Considered

<sup>&#</sup>x27;Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.